



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

PIEDMONT REGIONAL OFFICE

4949-A Cox Road, Glen Allen, Virginia 23060

(804) 527-5020 Fax (804) 527-5106

www.deq.virginia.gov

Molly Joseph Ward
Secretary of Natural Resources

David K. Paylor
Director

Michael P. Murphy
Regional Director

October DRAFT, 2016

Mr. David Crawford
Site Manager
AMPAC Fine Chemicals Virginia, LLC
2820 North Normandy Drive
Petersburg, VA 23805

Location: Petersburg
Registration No.: 50856

Dear Mr. Crawford:

Attached is a significant amendment to your state operating permit dated September 27, 2013 to operate a pharmaceutical production facility in accordance with the provisions of the Virginia Regulations for the Control and Abatement of Air Pollution. This amended permit supersedes your permit dated September 27, 2013.

The Department of Environmental Quality (DEQ) deemed the application complete on September 6, 2016 and has determined that the application meets the requirements of 9 VAC 5-80-990 A for a significant amendment to a state operating permit. The Department solicited written public comments by placing a newspaper advertisement in The Progress-Index on September 26, 2016. The required comment period provided by 9 VAC 5-80-1020A expired on October 26, 2016.

This permit contains legally enforceable conditions. Failure to comply may result in a Notice of Violation and/or civil charges. Please read all permit conditions carefully.

This permit approval to operate shall not relieve AMPAC Fine Chemicals Virginia, LLC of the responsibility to comply with all other local, state, and federal permit regulations.

The emergency generator and fire pumps may be subject to 40 CFR 63, Maximum Achievable Control Technology, (MACT) Subpart ZZZZ. Virginia has not accepted delegation of this rule. In summary, the units may be required to comply with certain federal emission standards and operating limitations. The Department of Environmental Quality (DEQ) advises you to review the referenced MACT

to ensure compliance with applicable emission and operational limitations. As the owner/operator you are also responsible for any monitoring, notification, reporting and recordkeeping requirements of the MACT. Notifications shall only be sent to EPA, Region III.

To review any federal rules referenced in the above paragraph or in the attached permit, the US Government Publishing Office maintains the text of these rules at www.ecfr.gov, Title 40, Part 63.

The Board's Regulations as contained in Title 9 of the Virginia Administrative Code 5-170-200 provide that you may request a formal hearing from this case decision by filing a petition with the Board within 30 days after this case decision notice was mailed or delivered to you. Please consult the relevant regulations for additional requirements for such requests.

As provided by Rule 2A:2 of the Supreme Court of Virginia, you have 30 days from the date you actually received this permit or the date on which it was mailed to you, whichever occurred first, within which to initiate an appeal of this decision by filing a Notice of Appeal with:

David K. Paylor, Director
Department of Environmental Quality
P. O. Box 1105
Richmond, VA 23218

If this permit was delivered to you by mail, three days are added to the thirty-day period in which to file an appeal. Please refer to Part Two A of the Rules of the Supreme Court of Virginia for information on the required content of the Notice of Appeal and for additional requirements governing appeals from decisions of administrative agencies.

If you have any questions concerning this permit, please contact the regional office at (804) 527-5020.

Sincerely,

James E. Kyle, P.E.
Air Permit Manager

JEK/clm/50856-19

Attachment: Permit
Source Testing Report Format
Attachment A

Cc: Manager/Inspector, Air Compliance
Chief, Air Enforcement Branch (3AP13), U.S. EPA, Region III



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Molly Joseph Ward
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Michael P. Murphy
Regional Director

STATIONARY SOURCE PERMIT TO OPERATE

This permit supersedes your permit dated September 27, 2013.

In compliance with the Federal Clean Air Act and the Commonwealth of Virginia Regulations for the Control and Abatement of Air Pollution,

AMPAC Fine Chemicals Virginia, LLC
2820 North Normandy Drive
Petersburg, VA 23805
Registration No.: 50856

is authorized to operate

a pharmaceutical production facility

located at

2820 North Normandy Drive
Petersburg, Virginia

in accordance with the Conditions of this permit.

Approved on October DRAFT, 2016.

James E. Kyle, P. E.
Air Permit Manager

Permit consists of 19 pages.
Permit Conditions 1 to 45.

INTRODUCTION

This permit approval is based on the permit application dated April 29, 2005, including amendment information dated May 31, 2005, June 2, 2005, June 10, 2005, June 16, 2005, June 21, 2005, August 8, 2005, July 27, 2006, August 8, 2006, August 9, 2006, August 29, 2006, March 21, 2007, March 26, 2007, September 29, 2013, July 1, 2016, and August 29, 2016. Any changes in the permit application specifications or any existing facilities which alter the impact of the facility on air quality may require a permit. Failure to obtain such a permit prior to construction may result in enforcement action.

Words or terms used in this permit shall have meanings as provided in 9 VAC 5-10-20 of the State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution. The regulatory reference or authority for each condition is listed in parentheses () after each condition.

Annual requirements to fulfill legal obligations to maintain current stationary source emissions data will necessitate a prompt response by the permittee to requests by the DEQ or the Board for information to include, as appropriate: process and production data; changes in control equipment; and operating schedules. Such requests for information from the DEQ will either be in writing or by personal contact.

The availability of information submitted to the DEQ or the Board will be governed by applicable provisions of the Freedom of Information Act, §§ 2.2-3700 through 2.2-3714 of the Code of Virginia, § 10.1-1314 (addressing information provided to the Board) of the Code of Virginia, and 9 VAC 5-170-60 of the State Air Pollution Control Board Regulations. Information provided to federal officials is subject to appropriate federal law and regulations governing confidentiality of such information.

Equipment List – Equipment at this facility consists of the following:		
Reference No.	Equipment Description	Rated Capacity
<i>Utility Building</i>		
FB-1	Boiler (Natural gas or propane)	20.9 MMBtu/hr
FB-2	Boiler (Natural gas or propane)	20.9 MMBtu/hr
<i>S1 Building</i>		
Bay 1	One reactor, three receivers, two process tanks, and related process equipment	--
Bay 2	One reactor, one process vessel, one distillation system, one mill system, one portable sifter, and related process equipment	--
Bay 3	Three reactors, five receivers, one centrifuge, one dryer, six process tanks, one separator, and related process equipment	--
Bay 6	Two reactors, nine process vessels, one centrifuge, one dryer, and related process equipment	--

Reference No.	Equipment Description	Rated Capacity
<i>S1 Building</i>		
Bay 7	Two reactors, six process vessels, one separator, one centrifuge, one dryer, and related process equipment	--
Bay 9	Two reactors, seven process vessels, one separator, one centrifuge, one dryer, and related process equipment	--
Bay 10	Four reactors, six process vessels, one centrifuge, one dryer, and related process equipment	--
Bay 10 Kettle	One reactor, one centrifuge, and related process equipment	--
<i>S2 Building</i>		
Bay 30	Two reactors, five process vessels, and related process equipment	--
FB-5	Distillate oil fired emergency generator	650 kW
<i>S3 Building</i>		
Bay 31 Pilot Plant	Two reactors, one portable reactor, two process vessels, one separator, one centrifuge, one dryer, one filter-dryer, and related process equipment	--
Bay 31 Kilo Lab	Two reactors, three process vessels, one separator, one dryer, and related process equipment	--
Bay 32	Two reactors, ten process vessels, one separator, two distillation systems, one centrifuge, one dryer, and related process equipment	--
Bay 33	Three reactors, ten process vessels, one separator, one centrifuge, one dryer, and related process equipment	--
Bay 34	Three reactors, nine process vessels, one separator, one centrifuge, one dryer, and related process equipment	--
FB-3	Boiler (Natural gas or propane)	1.8 MMBtu/hr
FB-4	Boiler (Natural gas or propane)	1.8 MMBtu/hr
<i>S5 Building</i>		
Bay 50	Four reactors, one centrifuge, one dryer, eight process vessels, and ancillary equipment	--
Bay 51	Three reactors, two centrifuges, one dryer, six process vessels, and ancillary equipment	--
Bay 52	Three reactors, one centrifuge, one dryer, six process vessels, and ancillary equipment	--
Bay 53	Three reactors, one centrifuge, one dryer, eight process vessels, and ancillary equipment	--

<i>RTO Area</i>		
RTO Control System consisting of:		
TO-2902	Anguil Environmental Systems Model RTO-300 Regenerative Thermal Oxidizer	30,000 scfm 7.4 MMBtu/hr
CL-2902	Anguil Environmental Systems Acid Gas Scrubber	30,000 scfm 470 gpm
<i>Tank Farm</i>		
TK-255	One fixed roof vertical storage tank (toluene) CAS # 108-86-3	10,000 gallons
TK-256	One fixed roof vertical storage tank (methanol) CAS # 67-56-1	10,000 gallons
TK-257	One fixed roof vertical storage tank (recovered toluene) CAS # 108-86-3	15,000 gallons
TK-258	One fixed roof vertical storage tank (organic liquid)	10,000 gallons
TK-259	One fixed roof vertical storage tank (ethanol) CAS # 65-17-5	10,000 gallons
TK-260	One fixed roof vertical storage tank (guaiacol) CAS # 90-05-1	10,000 gallons
TK-2601	One fixed roof vertical storage tank (organic liquid waste)	19,800 gallons
TK-2605	One fixed roof vertical storage tank (chlorinated liquid waste)	19,800 gallons
TK-2602 TK-2603 TK-2606 TK-2607 TK-2608 TK-2609	Six fixed roof vertical storage tanks of: Acetone (67-64-1), Acetonitrile (75-05-8), Butyl Acetate (123-86-4), Diglyme (111-96-6), Dimethylacetamide (127-19-5), Ethyl Acetate (141-78-6), Ethylene Glycol (107-21-1), Glycerol Monochlorohydrin (96-24-2), Methyl Cyclohexane (108-87-2), Methyl t-Butyl Ether (1634-04-4), and Tetrahydrofuran (109-99-9). **Note: All solvents will be used interchangeably in the six tanks.	19,800 gallons each
<i>Fire Water Pump House</i>		
FB-6A	Diesel emergency fire pump internal combustion engine	310 hp
FB-6B	Diesel emergency fire pump internal combustion engine	310 hp
<i>Wastewater Treatment Plant</i>		
	4 Covered neutralization basins	--
	Sequencing batch reactor system equipped with an in-situ oxygenator	--
	Effluent storage bins	--
	4 Post treatment air strippers	--

Specifications included in the above tables are for informational purposes only and do not form enforceable terms or conditions of the permit.

PROCESS REQUIREMENTS

1. **Emission Controls** – Particulate matter and PM₁₀ emissions from the S2 Building, the S3 building, and the S5 building shall be controlled by one or more baghouses. Particulate matter and PM₁₀ emissions from the S1 building shall also be controlled by one or more baghouses. Each baghouse shall be designed and sized appropriately for the airflow being filtered. Each baghouse shall be provided with adequate access for inspection. Each baghouse shall be equipped with a device to continuously measure the differential pressure drop across the baghouse. The device shall be installed in an accessible location and shall be maintained by the permittee such that it is in proper working order at all times.
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)
2. **Emission Controls** – Volatile organic compound emissions from the following bays shall be controlled by one or more condensation systems and one or more wet scrubbing systems except during hydrogen- or ethane-emitting processes, in which case the bays shall be controlled by one or more condensation systems:

Bay 3	Bay 31 Pilot Plant	Bay 50
Bay 6	Bay 31 Kilo Lab	Bay 51
Bay 7	Bay 32	Bay 52
Bay 9	Bay 33	Bay 53
Bay 10	Bay 34	

Each condensation system shall be equipped with an outlet vapor temperature gauge or a temperature gauge on the condensed liquid drain pipe. Each wet scrubbing system shall be equipped with a flow meter. If the VOC emissions from the bays listed above are not vented to the RTO Control System as allowed by the Alternate Operating Scenario specified in Condition 7, the permittee shall monitor and record the flow rate of the scrubbing medium at least once per operating day. All systems shall be provided with adequate access for inspection and shall be in operation when the permitted equipment is in operation.
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)

3. **Emission Controls** – Volatile organic compound emissions from Bay 30 shall be controlled by a condensation system using a suitable heat transfer medium. Each condensation system shall be equipped with an outlet vapor temperature gauge or a temperature gauge on the condensed liquid drain pipe. All systems shall be provided with adequate access for inspection and shall be in operation when the permitted equipment is in operation.
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)

4. **Emission Controls** – If VOC emissions are not vented to the RTO Control System, as allowed by the Alternate Operating Scenario specified in Condition 7, the primary condensers required by Conditions 2 and 3 shall maintain exhaust vapor temperatures on the outlet temperature gauges that comply with the following specifications (this Condition does not apply to Bays 50-53):

For $T_{\text{reactor}} < 18\text{ }^{\circ}\text{C}$	$T_{\text{exit vapor}} = T_{\text{reactor}}$
For $18\text{ }^{\circ}\text{C} \leq T_{\text{reactor}} \leq 30\text{ }^{\circ}\text{C}$	$T_{\text{exit vapor}} = 18\text{ }^{\circ}\text{C}$
For $30\text{ }^{\circ}\text{C} \leq T_{\text{reactor}} \leq 70\text{ }^{\circ}\text{C}$	$T_{\text{exit vapor}} = 25\text{ }^{\circ}\text{C}$
For $T_{\text{reactor}} \geq 70\text{ }^{\circ}\text{C}$	$T_{\text{exit vapor}} = T_{\text{reactor}} - 45\text{ }^{\circ}\text{C}$

If the permittee is using a temperature gauge on the condensed liquid drain pipe in lieu of an outlet vapor temperature gauge, the temperature of the condensed liquid drain pipe may be used in place of the exhaust vapor temperature for purposes of demonstrating compliance with this condition. The permittee shall monitor and record the exhaust vapor temperatures or the condensed liquid temperatures on the temperature gauges of the condenser systems and the reactor temperature data once per operating day. Reactor temperature data as well as exhaust vapor temperature data and condensed liquid temperature data shall be readily available during inspections and upon request of the Piedmont Regional Office. Compliance with the requirements of Condition 6 shall also indicate compliance with the requirements of this Condition. Failure to comply with the exhaust vapor temperature requirements when the RTO Control System is not in operation shall be considered a violation of this permit and may require a new or amended permit.

(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)

5. **Emission Controls** – Acid gas and base gas emissions from the following bays shall be controlled by a wet scrubbing system using a liquid medium that shall be process dependent:

Bay 1	Bay 30	Bay 50
Bay 2	Bay 31 Pilot Plant	Bay 51
Bay 3	Bay 31 Kilo Lab	Bay 52
Bay 6	Bay 32	Bay 53
Bay 7	Bay 33	
Bay 9	Bay 34	
Bay 10		

Each wet scrubbing system shall be equipped with a flow meter. When the batch train is emitting base gases, the permittee shall maintain the pH of the scrubbing medium to a level of 7.0 or less. When the batch train is emitting acid gases, the permittee shall maintain the pH of the scrubbing medium to a level of 7.0 or greater. . The permittee shall monitor and record the type of gas emitted and the pH of the scrubbing medium at least once per batch. Compliance with the requirements of Condition 6 shall also indicate compliance with the requirements of this Condition. The wet scrubbing systems shall be provided with adequate access for inspection and shall be in operation when the permitted equipment is operating.

(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)

6. **Emission Controls** – After control by the condensation systems and scrubbing systems required in Conditions 2, 3, and 5, the exhausts from the S1 building, the S2 building, the S3 building, and the S5 building shall be controlled by a regenerative thermal oxidizer (Ref. No. TO-2902) having a minimum destruction efficiency of 95.0% for VOC/HAP. The RTO Control System shall consist of a thermal oxidizer and an acid gas scrubber. The RTO acid gas scrubber (Ref. No. CL-2902) shall have a minimum control efficiency of 99.0% for hydrogen chloride. The RTO gas scrubber shall reduce emissions of SO₂ by 50% (weight) or to a SO₂ concentration of 20 ppmv, on a dry basis corrected to 3% oxygen, whichever is less stringent. Except as provided in Condition 7, the RTO shall be in operation when the bays in the S1 building, the S2 building, the S3 building, or the S5 building are in operation and shall be provided with adequate access for inspection.

The RTO shall have a chamber set point temperature of 1550 °F and a retention time of at least 0.5 seconds. A lower set point temperature may be used if the permittee has demonstrated during the most recent compliance test that the lower temperature provides the same amount of destruction as required by this permit. The oxidation chamber shall be equipped with a device to continuously measure the temperature of the chamber during operation. The facility shall continuously record and monitor the temperature of the chamber during operation.

Exhaust from the RTO shall be routed to the acid gas scrubber for the control of acid gases as appropriate. The acid gas scrubber shall be equipped with a flow meter showing the flow rate of scrubbing medium in gallons per minute. The permittee shall record the flow through the acid gas scrubber during operation once every 8 hours, at minimum. Additionally, the permittee shall measure and record the pH of the scrubbing medium during operation once every 8 hours, at a minimum. The permittee shall maintain the pH of the scrubbing medium to a level of 6.8 or greater.

The monitoring devices required by this condition shall be installed, calibrated, maintained, and operated in accordance with manufacturer's recommendations and good air pollution control practices.

(9 VAC 5-80-1180, 9 VAC 5-50-260, 9 VAC 5-80-850, 9 VAC 5-50-410, and 9 VAC 5-60-320)

7. **Alternate Operating Scenario** – Provided that facility-wide VOC emissions for the current 12-month period (calculated monthly by adding the total VOC emissions for the most recently completed calendar month to the individual monthly totals for the preceding 11 months) does not exceed 25 tons/yr, the permittee may elect to bypass the RTO Control System for emissions from all bays located in the S1 building (Bay 1, 2, 3, 6, 7, 9, and 10), the S2 building (Bay 30), the S3 Building (Bays 31-34, and batch train RE-9902), and new product development, provided that facility-wide HAP emissions are maintained below the emission limits contained in Condition 26. The permittee shall keep a log of the operating days on which the RTO Control System is bypassed.
(9 VAC 5-80-1180 and 9 VAC 5-80-850)

8. **Emission Controls** – Volatile organic compound emissions from the wastewater treatment plant shall be controlled by the use of covered neutralization basins and the use of a high purity oxygen system in the sequencing batch reactors. The wastewater treatment plant shall be provided with adequate access for inspection and shall have all control devices and work practices for the reduction of air pollution in operation while the wastewater treatment plant is operating.
(9 VAC 5-80-850)
9. **Emission Controls** – The permittee shall institute a component inspection and emission estimation program as described in Attachment A. When required, the Level 2 monitoring program shall demonstrate compliance with the following standards:
 - a. A minimum 98.3% of all valves, pressure relief devices, pump seals, and connectors shall monitor at default zero emission values.
 - b. The remaining valves, pressure relief devices, pump seals, and connectors shall monitor at or below 10,000 ppm.
(9 VAC 5-80-850)
10. **VOC Work Practice Standards** – At all times the disposal of volatile organic compounds shall be accomplished by taking measures, to the extent practicable, consistent with air pollution control practices for minimizing emissions. Volatile organic compounds shall not be intentionally spilled, discarded in sewers which are not connected to a treatment plant, or stored in open containers, or handled in any other manner that would result in evaporation beyond that consistent with air pollution practices for minimizing emissions.
(9 VAC 5-80-1180, 9 VAC 5-50-20 F, and 9 VAC 5-80-850)

OPERATING LIMITATIONS

11. **Operating Hours** – The 650 kW emergency generator (FB-5) and two emergency fire pumps (FB-6A and FB-6B) are to be used only for providing power at the location during interruption of services from the normal power supplier, periodic maintenance testing, and operational training. The generator and fire pumps shall each not operate more than 500 hours per year, calculated monthly as the sum of each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months. These records shall be available for inspection by the DEQ. Such records shall be current for the most recent five years.
(9 VAC 5-80-1180, 9 VAC 5-50-50, and 9 VAC 5-80-850)
12. **Fuel** – The approved fuels for the boilers (Ref. No. FB-1, FB-2, FB-3, and FB-4) and the RTO are natural gas and propane (as a backup). A change in the fuel may require a new or amended permit.
(9 VAC 5-80-1180 and 9 VAC 5-80-850)

13. **Fuel** – The approved fuels for the 650 kW emergency generator (FB-5) and two emergency fire pumps (FB-6A and FB-6B) are diesel fuel and distillate oil. The fuel shall meet either the ASTM D975 specification for S15 diesel fuel oil, or the ASTM D396 specification for numbers 1 or 2 fuel oil, with maximum sulfur content per shipment of 0.5%. A change in the fuels may require a new or amended permit.
(9 VAC 5-80-1180 and 9 VAC 5-80-850)

14. **Fuel Throughput** – The boilers FB-1 and FB-2 shall consume no more fuel than to provide a cumulative annual heat input of 366.2×10^9 Btu per year, calculated monthly as the sum of each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months. If a combination of the two fuels is used, then the quantities of natural gas and propane shall not exceed values that will allow the following equation to hold true:

$$(X) * (1,000 \text{ Btu/ft}^3) + (Y) * (91,500 \text{ Btu/gal}) \leq 366.2 \text{ Btu/yr}$$

where X = Number of cubic feet of natural gas burned in a year

Y = Number of gallons of propane burned in a year

(9 VAC 5-80-1180 and 9 VAC 5-80-850)

15. **Fuel Certification** – The permittee shall obtain a certification from the fuel supplier with each shipment of diesel fuel/distillate oil. Each fuel supplier certification shall include the following:
- The name of the fuel supplier;
 - The date on which the fuel was received;
 - The quantity of fuel delivered in the shipment;
 - A statement that the fuel complies with the American Society for Testing and Materials specifications (ASTM D975) for S15 diesel fuel oil or ASTM D396 for numbers 1 or 2 fuel oil; and
 - The sulfur content of the diesel fuel/distillate oil.

Fuel sampling and analysis, independent of that used for certification, as may be periodically required or conducted by DEQ may be used to determine compliance with the fuel specifications stipulated in Condition 13. Exceedance of these specifications may be considered credible evidence of the exceedance of emission limits.

(9 VAC 5-80-1180 and 9 VAC 5-80-850)

16. **Hazardous Air Pollutant Restrictions** – The facility shall not store, process, use, or produce, as specified in 40 CFR 63.11494(a)(2), methylene chloride or any other Hazardous Air Pollutant listed in Table 1 to Subpart VVVVVV of Part 63.
(9 VAC 5-80-850)

EMISSION LIMITS

17. **Emission Limits** – Emissions from the operation of the two boilers (Ref. No. FB-1 and FB-2) shall not exceed the limits specified below:

Particulate Matter	0.3 lbs/hr	1.4 tons/yr
PM ₁₀	0.3 lbs/hr	1.4 tons/yr
Nitrogen Oxides (as NO ₂)	8.7 lbs/hr	38.0 tons/yr
Carbon Monoxide	3.4 lbs/hr	15.1 tons/yr
Volatile Organic Compounds	0.2 lbs/hr	1.0 tons/yr

These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of emission limits. Compliance with these emission limits may be determined as stated in Conditions 12 and 14.

(9 VAC 5-50-260 and 9 VAC 5-80-850)

18. **Emission Limits** – Combustion emissions from the RTO (Ref. No. TO-2902) shall not exceed the limits specified below:

Nitrogen Oxides (as NO ₂)	1.5 lbs/hr	6.7 tons/yr
Carbon Monoxide	0.6 lbs/hr	2.7 tons/yr

These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Condition 12.

(9 VAC 5-50-260 and 9 VAC 5-80-850)

19. **Emission Limits** – Combustion emissions from the operation of the emergency generator (Ref. No. FB-5) shall not exceed the limits specified below:

Sulfur Dioxide	3.4 lbs/hr	0.9 tons/yr
Nitrogen Oxides (as NO ₂)	21.5 lbs/hr	5.4 tons/yr

Carbon Monoxide	5.7 lbs/hr	1.4 tons/yr
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These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Conditions 11, 13, and 15.
(9 VAC 5-80-850)

20. **Emission Limits** – Combustion emissions from the operation of the two emergency fire pumps (Ref. No. FB-6A and FB-6B) shall not exceed the limits specified below:

Nitrogen Oxides (as NO ₂)	21.1 lbs/hr	5.3 tons/yr
Carbon Monoxide	4.5 lbs/hr	1.1 tons/yr

These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Conditions 11, 13, and 15.
(9 VAC 5-80-850)

21. **Emission Limits** – Emissions from the operation of all bays located in the S1 building (Bay 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10), the S2 building (Bay 30), the S3 Building (Bays 31-34, and batch train RE-9902), the S5 building (Bays 50-53), and new product development that are exhausted from the RTO Control System, and/or from the bypass exhaust as provided in Condition 7, shall not exceed the limits specified below:

Sulfur Dioxide	564.5 lbs/hr	52.9 tons/yr
Volatile Organic Compounds	497.8 lbs/hr	72.2 tons/yr

These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Conditions 2, 3, 4, 5, 6, and 7.
(9 VAC 5-50-260, 9 VAC 5-60-300, and 9 VAC 5-80-850)

22. **Emission Limits** – Emissions from the operation of all bays located in the S1 building (Bay 1, 2, 3, 6, 7, 9, and 10), the S2 building (Bay 30), the S3 Building (Bays 31-34, and batch train RE-9902), the S5 building (Bays 50-53), and new product development shall not exceed the limits specified below:

Particulate Matter	2.1 lbs/hr	9.4 tons/yr
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PM ₁₀	2.1 lbs/hr	9.4 tons/yr
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These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Condition 1.

(9 VAC 5-50-260 and 9 VAC 5-80-850)

23. **Emission Limits** – Emissions from the operation of the wastewater treatment facility shall not exceed the limits specified below:

Volatile Organic Compounds	3.0 lbs/hr	13.0 tons/yr
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These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Condition 8.

(9 VAC 5-60-300 and 9 VAC 5-80-850)

24. **Emission Limits** – Fugitive emissions from connections, valves, pumps, flanges, etc. at the facility shall not exceed the limits specified below:

Volatile Organic Compounds	0.5 lbs/hr	2.0 tons/yr
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These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Condition 9.

(9 VAC 5-60-300 and 9 VAC 5-80-850)

25. **Facility-wide Emission Limits** – Total emissions from the pharmaceutical manufacturing facility shall not exceed the limits specified below:

Particulate Matter	4.4 lbs/hr	11.6 tons/yr
PM ₁₀	4.4 lbs/hr	11.6 tons/yr
Sulfur Dioxide	569.3 lbs/hr	54.2 tons/yr
Nitrogen Oxides (as NO ₂)	54.6 lbs/hr	58.9 tons/yr
Carbon Monoxide	15.0 lbs/hr	21.7 tons/yr
Volatile Organic Compounds	540.2 lbs/hr	89.7 tons/yr

These emissions are derived from the estimated overall emission contribution from operating limits. Exceedance of the operating limits may be considered credible evidence of the exceedance of emission limits. Compliance with these emission limits may be determined as stated in Conditions 1 – 15.

(9 VAC 5-80-1180 and 9 VAC 5-80-850)

26. **Facility-wide Emission Limits** – Hazardous air pollutant (HAP) emissions, as defined by §112(b) of the Clean Air Act, from the facility shall not exceed 9.4 tons per year of any individual HAP or 24.4 tons per year of any combination of HAPs, calculated monthly as the sum of each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months.
(9 VAC 5-80-850)
27. **Volatile Organic Compounds Emission Factors** – The permittee shall evaluate the emission rate of volatile organic compounds to be emitted by a new chemical production process or a change to an existing process. The permittee shall develop the necessary emission factor(s) for the new process or the change to the existing process so that calculations may be reviewed at the plant site and used to support facility-wide emission calculations.
(9 VAC 5-80-850)
28. **Visible Emission Limit** – Visible emissions from any baghouse at the facility shall not exceed five percent opacity as determined by EPA Method 9 (reference 40 CFR 60, Appendix A).
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)
29. **Visible Emission Limit** – Visible emissions from each boiler (Ref. No. FB-1 and FB-2) shall not exceed 10 percent opacity except during one six-minute period in any one hour in which visible emissions shall not exceed 20 percent opacity. This condition applies at all times except during start-up, shutdown, or malfunction.
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)
30. **Visible Emission Limit** – Visible emissions from the RTO (Ref. No. TO-2902) and acid gas scrubber (Ref. No. CL-2902) shall not exceed five percent opacity as determined by EPA Method 9 (reference 40 CFR 60, Appendix A).
(9 VAC 5-80-1180, 9 VAC 5-50-260, and 9 VAC 5-80-850)

COMPLIANCE DETERMINATIONS

31. **RTO Control System Stack Tests** – If monitoring data, process changes, operational changes made to the RTO Control System, or other data indicates the need for re-testing the RTO Control System to demonstrate compliance with the limits in this permit, the permittee shall submit a test protocol for such tests at least 45 days prior to testing and shall arrange the details of the test

with the Piedmont Regional Office. One copy of any test results shall be submitted to the Piedmont Regional Office within 45 days after test completion.
(9 VAC 5-50-30, 9 VAC 5-80-1200, and 9 VAC 5-80-850)

32. **Emission Factor Verification Testing** – Every five years (starting from the date of this permit), the permittee shall submit to the Piedmont Regional Office a test protocol, the purpose of which is to verify emission factors used in the process emission rate calculations. The test(s) shall be conducted at the inlet to the RTO Control System for a duration of approximately 12 hours. Total VOCs shall be determined by monitoring total organic concentration either via 40 CFR 60, Appendix A Method 25A or using the monitoring equipment that meets current testing specifications. The emission factor verification shall consist of a comparison between the results of the test(s) and the predicted total VOC emissions, calculated using the emission factors for the production sequences occurring during the time of the test. The permittee may, with the written approval of the Piedmont Regional Office, use an alternate test method for emission factor verification. Upon approval of the test protocol by the Piedmont Regional Office, the permittee shall perform the tests within 60 days of the date of approval. The permittee shall submit one copy of these test results to the Piedmont Regional Office within 45 days after test completion.
(9 VAC 5-50-30 and 9 VAC 5-80-850)

RECORDS

33. **On Site Records** – The permittee shall maintain records of emission data and operating parameters as necessary to demonstrate compliance with this permit. The content and format of such records shall be arranged with the Piedmont Regional Office. These records include, but are not limited to:
- a. Operating parameters, including:
 - i. Outlet vapor temperature records required in Conditions 3 and 4 of this permit;
 - ii. Flow and pH records for the acid gas scrubber required in Conditions 2 and 5 of this permit;
 - iii. RTO chamber temperature records required in Condition 6 of this permit; and
 - iv. A log of the operating days on which the RTO is bypassed as required in Condition 7 of this permit.

b. Fuel usage records, including:

- i. Annual hours of operation of the emergency generator (Ref. No. FB-5), calculated as the sum of the hours of operation during each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months;
- ii. Annual hours of operation by the fire pump engines (Ref. Nos. FB-6A and FB-6B), calculated as the sum of the hours of operation during each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months;
- iii. Annual consumption of natural gas for the boilers (FB-1, FB-2, FB-3 and FB-4) and for the RTO, calculated as the sum of the consumption during each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months;
- iv. Annual consumption of propane for the boilers (FB-1, FB-2, FB-3 and FB-4) and for the RTO, calculated as the sum of the consumption during each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months;
- v. Monthly records of all diesel shipments purchased, indicating the sulfur content per shipment; and
- vi. Records and calculations demonstrating compliance with Condition 14. Compliance shall be determined monthly, as the sum of the previous consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months.

c. Emissions data, including:

- i. Stack test data;
- ii. Emission factor verification data, to include emission factors for each chemical produced, all VOC and HAP calculations required for each emission factor, and quantities of each chemical produced;

- iii. Fugitive component inspection and emissions estimation program records, including records required by Attachment A and those necessary to demonstrate compliance with Condition 9; and
- iv. Monthly and annual emission calculations to verify compliance with the individual and total HAP emission limitations in Condition 26. Annual emissions shall be calculated monthly as the sum of each consecutive 12-month period. Compliance for the consecutive 12-month period shall be demonstrated monthly by adding the total for the most recently completed calendar month to the individual monthly totals for the preceding 11 months. Calculations shall be performed as in the application and supplemental information listed in the Introduction, to include control efficiency requirements.

These records shall be available for inspection by the DEQ and shall be current for the most recent five years.

(9 VAC 5-80-1180, 9 VAC 5-50-50, and 9 VAC 5-80-900)

REPORTING

- 34. **Process Change Reporting** – The permittee shall submit a report to the Piedmont Regional Office documenting the basis each emission factor developed for each process change as required in Condition 27. The documentation shall be submitted within 30 days after implementing the change. It shall include, as a minimum, the date of the change and information sufficient to justify emission factors used in calculating plant emissions.
(9 VAC 5-50-50)

TESTING

- 35. **Emission Testing** – The facility shall be constructed so as to allow for emissions testing upon reasonable notice at any time, using appropriate methods. This includes constructing the facility/equipment such that volumetric flow rates and pollutant emission rates can accurately be determined by applicable test methods and providing a stack or duct that is free from cyclonic flow. Sampling ports shall be provided when requested at the appropriate locations and safe sampling platforms and access shall be provided.
(9 VAC 5-80-880 and 9 VAC 5-80-850)

GENERAL CONDITIONS

- 36. **Right of Entry** – The permittee shall allow authorized local, state, and federal representatives, upon the presentation of credentials:
 - a. To enter upon the permittee's premises on which the facility is located or in which any records are required to be kept under the terms and conditions of this permit;

- b. To have access to and copy at reasonable times any records required to be kept under the terms and conditions of this permit or the State Air Pollution Control Board Regulations;
- c. To inspect at reasonable times any facility, equipment, or process subject to the terms and conditions of this permit or the State Air Pollution Control Board Regulations; and
- d. To sample or test at reasonable times.

For purposes of this condition, the time for inspection shall be deemed reasonable during regular business hours or whenever the facility is in operation. Nothing contained herein shall make an inspection time unreasonable during an emergency.
(9 VAC 5-170-130 and 9 VAC 5-80-850)

- 37. **Notification for Facility or Control Equipment Malfunction** - The permittee shall furnish notification to the Piedmont Regional Office of malfunctions of the affected facility or related air pollution control equipment that may cause excess emissions for more than one hour, by facsimile transmission, telephone, or telegraph. Such notification shall be made as soon as practicable but no later than four daytime business hours after the malfunction is discovered. The permittee shall provide a written statement giving all pertinent facts, including the estimated duration of the breakdown, within two weeks of discovery of the malfunction. When the condition causing the failure or malfunction has been corrected and the equipment is again in operation, the permittee shall notify the Piedmont Regional Office in writing.
(9 VAC 5-20-180 C and 9 VAC 5-80-850)
- 38. **Violation of Ambient Air Quality Standard** - The permittee shall, upon request of the DEQ, reduce the level of operation or shut down a facility, as necessary to avoid violating any primary ambient air quality standard and shall not return to normal operation until such time as the ambient air quality standard will not be violated.
(9 VAC 5-20-180 I and 9 VAC 5-80-850)
- 39. **Maintenance/Operating Procedures** – At all times, including periods of start-up, shutdown, and malfunction, the permittee shall, to the extent practicable, maintain and operate the affected source, including associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions.

The permittee shall take the following measures in order to minimize the duration and frequency of excess emissions, with respect to air pollution control equipment and process equipment which affect such emissions:

- a. Develop a maintenance schedule and maintain records of all scheduled and non-scheduled maintenance.
- b. Maintain an inventory of spare parts.

- c. Have available written operating procedures for equipment. These procedures shall be based on the manufacturer's recommendations, at a minimum.
- d. Train operators in the proper operation of all such equipment and familiarize the operators with the written operating procedures, prior to their first operation of such equipment. The permittee shall maintain records of the training provided including the names of trainees, the date of training and the nature of the training.

Records of maintenance and training shall be maintained on site for a period of five years and shall be made available to DEQ personnel upon request.

(9 VAC 5-50-20 E and 9 VAC 5-80-850)

40. **Permit Suspension/Revocation** - This permit may be revoked if the permittee:

- a. Knowingly makes material misstatements in the permit application or any amendments to it;
- b. Fails to comply with the terms or conditions of this permit;
- c. Fails to comply with any emission standards applicable to a permitted emissions unit;
- d. Causes emissions from this facility which result in violations of, or interferes with the attainment and maintenance of, any ambient air quality standard;
- e. Fails to operate this facility in conformance with any applicable control strategy, including any emission standards or emission limitations, in the State Implementation Plan in effect at the time that an application for this permit is submitted; or
- f. Fails to comply with the applicable provisions of Articles 6, 8 and 9 of 9 VAC 5 Chapter 80.

(9 VAC 5-80-1010)

41. **Change of Ownership** - In the case of a transfer of ownership of a stationary source, the new owner shall abide by any current permit issued to the previous owner. The new owner shall notify the Piedmont Regional Office of the change of ownership within 30 days of the transfer.
(9 VAC 5-80-940)

42. **Permit Copy** - The permittee shall keep a copy of this permit on the premises of the facility to which it applies.
(9 VAC 5-80-860 D)

STATE-ONLY ENFORCEABLE REQUIREMENTS

43. **Toxics** – The permittee shall evaluate the emission rate of each toxic air pollutant to be emitted by a new chemical production process or a change in an existing process as follows:

- a. The total potential to emit of each toxic air pollutant to be emitted by the facility shall be compared to the appropriate exemption level per 9 VAC 5-60-300 C 1. If the potential to emit of each toxic air pollutant is less than the respective exemption limit, the process or process change may be utilized as long as all other conditions of this permit are satisfied.
- b. If the potential to emit of the toxic air pollutant is greater than the respective exemption level, the permittee shall compare the potential to emit with the value used in the most recent, approved atmospheric dispersion modeling that demonstrates that the SAAC is not exceeded. If the potential to emit of the toxic air pollutant is less than the value used in the most recent, approved atmospheric dispersion model, the process or process change may be utilized as long as all other conditions of the permit are satisfied.
- c. If the potential to emit of the toxic air pollutant is greater than the value used in the most recent, approved atmospheric dispersion model, the permittee shall supply to the Piedmont Regional Office atmospheric dispersion modeling acceptable to the Department that demonstrates the SAAC is not exceeded or shall make process changes that lower the potential to emit of the toxic air pollutant.

For the purposes of this condition, “toxic air pollutant” is defined as any hazardous air pollutant listed in Title III, Section 112(b) of the Clean Air Act Amendments of 1990, as amended.
(9 VAC 5-80-850 and 9 VAC 5-60-300)

44. **On Site Records** – The permittee shall maintain toxic air pollutant emission records sufficient to document compliance with operations as authorized under Condition 43. The content and format of such records shall be arranged with the Piedmont Regional Office. These records shall be available for inspection by the DEQ and shall be current for the most recent five years.
(9 VAC 5-80-1180, 9 VAC 5-50-50, and 9 VAC 5-80-900)
45. **Process Change Reporting** – The permittee shall submit a report to the Piedmont Regional Office documenting the basis for each process change as authorized in Condition 43. The documentation shall be submitted within 30 days after implementing the change. It shall include, as a minimum, the date of the change and information sufficient to show the change is authorized per this permit.
(9 VAC 5-50-50)

SOURCE TESTING REPORT FORMAT

Report Cover

1. Plant name and location
2. Units tested at source (indicate Ref. No. used by source in permit or registration)
3. Test Dates.
4. Tester; name, address and report date

Certification

1. Signed by team leader/certified observer (include certification date)
2. Signed by responsible company official
3. *Signed by reviewer

Copy of approved test protocol

Summary

1. Reason for testing
2. Test dates
3. Identification of unit tested & the maximum rated capacity
4. *For each emission unit, a table showing:
 - a. Operating rate
 - b. Test Methods
 - c. Pollutants tested
 - d. Test results for each run and the run average
 - e. Pollutant standard or limit
5. Summarized process and control equipment data for each run and the average, as required by the test protocol
6. A statement that test was conducted in accordance with the test protocol or identification & discussion of deviations, including the likely impact on results
7. Any other important information

Source Operation

1. Description of process and control devices
2. Process and control equipment flow diagram
3. Sampling port location and dimensioned cross section Attached protocol includes: sketch of stack (elevation view) showing sampling port locations, upstream and downstream flow disturbances and their distances from ports; and a sketch of stack (plan view) showing sampling ports, ducts entering the stack and stack diameter or dimensions

Test Results

1. Detailed test results for each run
2. *Sample calculations
3. *Description of collected samples, to include audits when applicable

Appendix

1. *Raw production data
2. *Raw field data
3. *Laboratory reports
4. *Chain of custody records for lab samples
5. *Calibration procedures and results
6. Project participants and titles
7. Observers' names (industry and agency)
8. Related correspondence
9. Standard procedures

* Not applicable to visible emission evaluations

ATTACHMENT A

Component Inspection and Estimation Program

The Component Inspection and Emission Estimation Program is summarized in Table A-1 below:

Table A-1

Equipment	Level 1 Monitoring	Level 2 Monitoring*
Pressure or vacuum reactor system components	Batch process equipment may be pressure or vacuum tested prior to each batch campaign, as an alternative to the monitoring requirements stated in the following conditions. Testing will be conducted no less often than annually.	Same as Level 1 monitoring.
Pressure relief devices	Visual, audible, or olfactory inspections for leaks after each event.	Level 1 monitoring, plus Method 21 monitoring after each pressure relief event. Method 21 monitoring is not required if a rupture disc is placed in line prior to the pressure relief device.
Pumps Connectors Valves	Monthly visual, audible, or olfactory inspection for leaks. Quarterly inspections may begin if no equipment leaks are detected for two successive months. Semiannual inspections may begin if no equipment leaks are detected for four successive quarters.	Level 1 monitoring, plus monthly monitoring by Method 21. Quarterly inspections may begin if no equipment leaks are detected for two successive months. Semiannual inspections may begin if no equipment leaks are detected for four successive quarters.
Open-ended valves and lines	Monthly visual, audible, or olfactory inspections for leaks. Quarterly inspections may begin if no equipment leaks are detected for two successive months. Semiannual inspections may begin if no equipment leaks are detected for four successive quarters.	Same as Level 1 monitoring.
Sample connection systems	Monthly visual, audible, or olfactory inspections for leaks. Quarterly inspections may begin if no equipment leaks are detected for two successive months. Semiannual inspections may begin if no equipment leaks are detected for four successive quarters.	Same as Level 1 monitoring.

* Under Level 2, a leak is considered found if Method 21 monitoring detects 10,000 ppm or greater.

A two level program shall be used, as follows:

- Level 1 monitoring is required if the 12 month rolling totals of emissions are less than 75% of the annual permit limits for VOC's as well as individual and total HAPs as stated in Conditions 25 and 26.
- Level 2 monitoring is required if the 12 month rolling total is equal to or greater than 75% of the annual permit limits for VOC's, individual HAPs, or total HAPs as stated in Conditions 25 and 26 for three consecutive months.

Monitoring may revert to Level 1 from Level 2 if the 12 month rolling totals are less than 75% of the annual permit limits for VOC's, individual HAPs, and total HAPs as stated in Conditions 25 and 26 for three consecutive months.

Monitoring frequency shall revert to monthly, or as specified in Table A-1, from either quarterly or semiannual inspection frequencies upon the detection of any leaks. Monthly inspections shall commence the following month from when the leak was discovered.

When a leak is detected under Level 1 or Level 2 monitoring, the leak shall be repaired as soon as practicable, but not later than 15 calendar days after it is detected. If the repair cannot be completed within 15 calendar days of detecting the leak, a report shall be submitted to the Piedmont Regional Office stating why the repair cannot be completed, and when the repair is expected to be complete. The report shall be submitted within 15 calendar days of detecting the leak.

All equipment at the facility that is in either VOC or HAP service shall be included in the component inspection and emission estimation program.

A form for each process unit shall be available on-site listing at least the inspection date, tag number for each component, type, service, results of inspection, and if found to be leaking, the date the leak was repaired. The inspector's initials shall also be included.